## REMARKS

Applicant respectfully traverses the restriction requirement of Groups I-IV on the grounds that the subject matter of the required search is sufficiently small and closely related as to be capable of examination together. The search would not be a burden on the Examiner.

The Office has characterized Groups I-III as unrelated because the different inventions are not disclosed as capable of use together and have different designs. Additionally, the Office has characterized Groups I-III and Group IV as unrelated because the Groups are drawn to a gene therapy vector which encompasses vectors other than the adenoviral vector and they have different modes of operation. However, the Office's position that the inventions are unrelated is based only on allegation; there has been no "showing" that in fact the different groups of claims or inventions are unrelated as required by MPEP 808.02.

Applicant has presented a generic invention with a generic claim and set forth a number of embodiments falling within the generic invention. It is submitted that 37 C.F.R. § 1.141 points out that distinct inventions may not form a single general inventive concept and may not be claimed in one application. However, the rule states that more than one species of an invention may be specifically claimed in different claims in one application, provided the application also includes an allowable generic claim and all the claims to the species in excel of one are written in dependent form or otherwise include all of the limitations of the generic claim. It is submitted that is precisely the situation in this application. Claim 1 is generic for gene therapy vectors. Claims 2 through 13 are written in dependent form and set forth a number of embodiments falling within the generic invention. The restriction between Groups I-III is, in effect, a species election because the Examiner requests restriction between polynucleotides encoding the cdtB gene from the species *H. ducreyi*, *C. jejuni*, and *E. coli.* The claims include all of the limitations of the generic claim. Therefore, as species of an allowable generic claim

which contain all of the limitations of the generic claim, claims 2-13 comply with 37 C.F.R. § 1.141 and the requirement for restriction should be withdrawn.

Similarly, claims 14 through 17 set forth a number of embodiments falling within the generic invention of claim 1. Although claims 14 through 17 are not dependent on claim 1, they include all of the limitations of the generic claim. As such, claims 14 through 17 read on and should be examined with claims 1 through 13.

Moreover, Groups I-IV have been classified in the Office Action in precisely the same class and subclass, *i.e.*, class 536, subclass 24.5. In view of the common class and subclass identified in the Office Action for each of the groups, the claims in Groups I-IV should be examined together. Therefore the requirement for restriction is improper.

Next, the Office has characterized Groups I-IV and Group V as unrelated because the method of conducting cytolethal gene therapy can be practiced using naked DNA, which is materially different than a gene therapy vector comprising a first polynucleotide a second polynucleotide operably linked to a promoter.

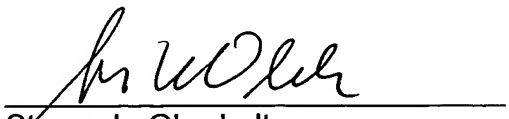
Applicant respectfully traverses the requirement of restriction of Groups I-IV and Group V because it is clear from the application that the method of conducting cytolethal gene therapy with naked DNA is not materially different from a gene therapy vector comprising a first and second polynucleotide operably linked to a promoter. The Applicant respectfully directs the Examiner's attention to paragraph 36 of the patent application. This paragraph addresses conducting cytolethal gene therapy using naked DNA and states: "In this case, use of the construct itself, *i.e.*, naked DNA, as the vector may be suitable." Paragraph 36 further states that "the construct of the present invention itself can be considered a vector in accordance with the present invention. That is, the construct comprising the gene encoding the cdtB subunit gene, the antisense oligonucleotide, and the inducible promoter operably linked to these elements can, by itself, comprise the vector of the present invention." (emphasis added) Accordingly, it is clear from paragraph 36 that using naked DNA is not materially different than a gene therapy vector comprising a first polynucleotide and a second

polynucleotide operably linked to a promoter. Therefore, the Applicant respectfully requests that the restriction requirement is withdrawn.

## SUMMARY

Applicant respectfully submits that the present application is now in condition for examination. Should the Examiner feel a discussion would expedite the prosecution of this application; the Examiner is kindly invited to contact the undersigned at (734) 302-6030.

Respectfully submitted,



Steven L. Oberholtzer
Registration No. 30,670
Attorney for Applicant
Customer No. – 00757 Brinks Hofer Gilson & Lione

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200